



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Data and Specimen Hub (DASH) (Eunice Kennedy Shriver National Institute of Child Health and Human Development)

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Rohan Hazra, M.D., Eunice Kennedy Shriver National

Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6710B Rockledge Drive, Room 2113, Bethesda, MD 20817, or call non-toll-free number (301)-435-6868 or E-mail your request, including your address to: rohan.hazra@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Data and Specimen Hub (DASH)-0925-0744 expiration date 06/30/2019, REVISION, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection:

This is a request to revise the previously approved submission to add the collection of additional information from Users who will request biospecimens, submit

the Institutional Certification for data/biospecimen inventory, and submit DASH data/biospecimen Annual Progress Report for the NICHD Data and Specimen Hub (DASH). DASH has been established by NICHD as a data sharing mechanism for biomedical research investigators. It serves as a centralized resource for investigators to store and access de-identified study data and biospecimen inventories – a list of biospecimens available at the NICHD Biorepository – from studies funded by NICHD. The potential for public benefit to be achieved through sharing study data and/or biospecimen inventories for secondary analysis is significant. NICHD DASH supports NICHD’s mission to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation. Study data and biospecimen sharing and reuse will promote testing of new hypotheses from data already collected, facilitate trans-disciplinary collaboration, accelerate scientific findings and enable NICHD to maximize the return on its investments in research.

Anyone can access NICHD DASH to browse and view descriptive information about the studies and study data archived in NICHD DASH without creating an account. Users who wish to submit or request research data and/or biospecimen inventories must register for an account.

Information will be collected from those wishing to create an account, sufficient to identify them as unique Users. Those submitting or requesting data and/or biospecimen inventories will be required to provide additional supporting information to ensure proper

use and security of NICHD DASH study data and biospecimen inventories. The information collected is limited to the essential data required to ensure the management of Users in NICHD DASH is efficient and the sharing of data and biospecimens among investigators is effective. The primary uses of the information collected from Users by NICHD will be to:

- Communicate with the Users with regards to their data submission, data requests and biospecimen requests
- Monitor data submissions, data requests and biospecimen requests
- Notify interested recipients of updates to data and biospecimen inventories stored in NICHD DASH
- Help NICHD understand the use of NICHD DASH study data and biospecimen inventories by the research community

All the data collected from use of NICHD DASH except for information provided in the annual progress reports are for the purposes of internal administrative management of NICHD DASH. Information gathered through the annual progress reports may be used in publications describing performance of the DASH system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 204.

Estimated Annualized Burden Hours

| Type of Form | Number of Respondents | Frequency of Response | Average Time Per Response (in hours) | Total Annual Burden Hour |
|---|-----------------------|-----------------------|--------------------------------------|--------------------------|
| User Registration | 200 | 1 | 5/60 | 17 |
| Data and Biospecimen Inventory Submission | 36 | 1 | 2 | 72 |
| Data Request | 60 | 1 | 1 | 60 |
| Biospecimen Request | 36 | 1 | 1 | 36 |
| Data Use Annual Progress Report | 60 | 1 | 10/60 | 10 |
| Biospecimen Use Annual Progress Report | 36 | 1 | 10/60 | 6 |
| Institutional Certification Template | 36 | 1 | 5/60 | 3 |
| TOTAL | 200 | 200 | | 204 |

Dated: April 17, 2018.

Jennifer M. Guimond,

Project Clearance Liaison,

Eunice Kennedy Shriver National Institute of Child Health and Human Development,

National Institutes of Health.

[FR Doc. 2018-08901 Filed: 4/26/2018 8:45 am; Publication Date: 4/27/2018]